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<b>TRANSMITTAL FORM</b> (to be used for all correspondence after initial filing)	Application Number	10/527,421 ✓
	Filing Date	September 10, 2003
	First Named Inventor	Cullen, Breda M.
	Art Unit	
	Examiner Name	
Total Number of Pages in this Submission	Attorney Docket Number	22050-1

**ENCLOSURES (check all that apply)**

<input type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached Credit Card Payment Form  <input type="checkbox"/> Amendment Response <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s)  <input type="checkbox"/> Extension of Time Request  <input type="checkbox"/> Express Abandonment Request  <input type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Documents  <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s)  <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition  <input type="checkbox"/> Petition to Convert a Provisional Application  <input type="checkbox"/> Power of Attorney, Revocation, Change of Correspondence Address  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Request for Refund  <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC  <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences  <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)  <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter  <input checked="" type="checkbox"/> Return Receipt Postcard  <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<b>Remarks</b> Third Party Submission under 37 CFR 1.99		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name	Woodard, Emhardt, Moriarty, McNett & Henry LLP	
Signature		
Printed Name	Kenneth A. Gandy	
Date	September 6, 2006	Reg. No. 33,386

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Date

Signature



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

Cullen, Breda M. et al.

Application No. 10/527,421

Filed: September 10, 2003

WOUND DRESSING MATERIALS  
COMPRISING COMPLEXES OF ANIONIC)  
POLYSACCHARIDES WITH SILVER )

) Examiner

)

) Group Art Unit:

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) September 6, 2006

Date of Deposit September 6, 2006

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*Kenneth A. Gandy*  
Signature of person mailing paper or fee

**THIRD PARTY SUBMISSION UNDER 37 CFR 1.99**

Assistant Commissioner of Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Pursuant to the provisions of 37 CFR § 1.99, the following publications are submitted for consideration by the Patent Office:

1. Examination Report from corresponding EP 03795068.0, October 27, 2005
2. Examination Report from corresponding GB 0221062.3, August 1, 2005

The fee under 37 CFR 1.17(p) is enclosed. Please charge any additional fee that may be necessary to Deposit Account No. 23-3030.

Respectfully submitted:

By:

*Kenneth A. Gandy*  
Kenneth A. Gandy, Reg. No. 31,286  
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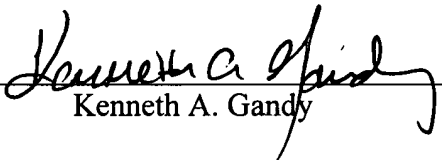


**CERTIFICATE OF SERVICE**

I, Kenneth A. Gandy, hereby certify that on this date I served a copy of the foregoing  
THIRD PARTY SUBMISSION UNDER 37 CFR 1.99 upon Applicant's Attorney of Record by  
depositing a copy thereof in the United States Mail, first class, postage prepaid and addressed as  
follows:

Philip S. Johnson  
Johnson & Johnson  
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NJ 08933-7003  
US

On this 6th of September, 2006.

By:   
Kenneth A. Gandy



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(Formalities and other matters)



Application No. 03 795 068.0 - 1219	Ref. P031748EP/ACJ	Date 27.10.2005
Applicant Johnson & Johnson Medical Ltd.		

**Communication pursuant to Article 96(2) EPC**

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

**of 4 months**

from the notification of this communication, this period being computed in accordance with Rules 78(2) and 83(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (Rule 36(1) EPC).

**Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Article 96(3) EPC).**



Espinosa y Carretero  
Primary Examiner  
for the Examining Division

Enclosure(s): 5 page/s reasons (Form 2906)

**Bescheld/Protokoll (Anlage)**

Datum  
Date 27.10.2005  
Date

**Communication/Minutes (Annex)**

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Sheet 1  
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**Notification/Procès-verbal (Annexe)**

Anmelde-Nr.:  
Application No.: 03 795 068.0  
Demande n°:

The examination is being carried out on the **following application documents**:

**Description, Pages**

1-24 as originally filed

**Claims, Numbers**

1-15 as originally filed

**Drawings, Sheets**

1/6-6/6 as originally filed

**1.Documents cited**

Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure:

- D1: WO 98/00180 A (WATT PAUL WILLIAM ;HARVEY WILSON (GB); LORIMER ELAINE (GB); JOHNSO) 8 January 1998 (1998-01-08)
- D2: WO 00/09173 A (LARSEN KIM LAMBERTSEN ;SAMUELSEN PETER BOMAN (DK); COLOPLAST AS (D) 24 February 2000 (2000-02-24)
- D3: WO 96/13282 A (INNOVATIVE TECH LTD ;QIN YIMIN (GB); GILDING KEITH DENNIS (GB)) 9 May 1996 (1996-05-09)
- D4: CHOI Y S ET AL: "STUDIES ON GELATIN-BASED SPONGES. PART III: A COMPARATIVE STUDY OF CROSS-LINKED GELATIN/ALGINATE, GELATIN/HYALURONATE AND CHITOSAN/HYALURONATE SPONGES AND THEIR APPLICATION AS A WOUND DRESSING IN FULL-THICKNESS SKIN DEFECT OF RAT" JOURNAL OF MATERIALS SCIENCE. MATERIALS IN



MEDICINE, CHAPMAN AND HALL, LONDON, GB, vol. 12, no. 1, 2001, pages 67-73, XP009007057 ISSN: 0957-4530

- D5: CHO Y-S ET AL: "HYALURONIC ACID AND SILVER SULFADIAZINE-IMPREGNATED POLYURETHANE FOAMS FOR WOUND DRESSING APPLICATION" JOURNAL OF MATERIALS SCIENCE. MATERIALS IN MEDICINE, CHAPMAN AND HALL, LONDON, GB, vol. 13, no. 9, 2002, pages 861-865, XP009007039 ISSN: 0957-4530
- D6: WO 02/24240 A (WOODS DAVID MALCOLM ;ACORDIS SPECIALTY FIBRES LTD (GB)) 28 March 2002 (2002-03-28)
- D7: WO 02/36866 A (GROOCKOCK MELANIE RACHEL ;QIN YIMIN (GB); SSL INTERNAT PLC (GB)) 10 May 2002 (2002-05-10)
- D8: WO 01/24839 A (ACRYMED ;GIBBINS BRUCE L (US); HOPMAN LANCE D (US)) 12 April 2001 (2001-04-12)

## 2.Novelty

Document D1 discloses the use of oxidized cellulose (oxidized regenerated cellulose) and complexes thereof with proteins (e.g. collagen) for the preparation of wound dressings for the treatment of chronic wounds. It may also contain antiseptics (e.g. silver sulfadiazine or chlorhexidine) (see page 5, lines 19-20).

The subject-matter of claims 1-15 differs from D1 by the presence of the complex of the anionic polysaccharide and silver and is therefore new over D1 according to Art. 54 EPC.

Document D2 discloses a stabilised composition having antibacterial, antiviral and/or antifungal activity which comprises a silver compound (e.g. silver acetate, silver nitrate or silver lactate, see page 7, lines 5-8) in the form of a complex with carboxymethylcellulose (see example) used in wound dressings (see claims 1 and 7-8).

Therefore the subject-matter of claims 1-8, 10-12 and 14 is not new according to Art. 54 EPC.

Document D3 describes a wound dressing comprises in combination a first wound contact layer which delivers a component to the wound (e.g. silver), such as silver alginate, silver N,O-carboxymethyl chitosan or silver O-carboxymethyl chitosan, and a second layer of greater hydrophilicity than the first layer.



Since D3 does not specify the amount of silver present in the wound dressing, the subject-matter of claims 1-15 of the present application is new with respect to D3 under Art. 54 EPC.

Documents D4 and D5 describe wound dressings containing polysaccharides (hyaluronic acid) and silver sulfadiazine showing improved wound healing properties without any inflammation.

The subject-matter of claims 1-15 differs from D4 and D5 by the presence of the complex of the anionic polysaccharide and silver and is therefore new over D4 and D5 according to Art. 54 EPC.

Document D6 describes wound dressings comprising polysaccharide fibres bonded with silver cations.

Therefore the subject-matter of claims 1-8, 10-12 and 14 is not new according to Art. 56 EPC.

Document D7 describes wound dressings comprising fibres (e.g. carboxymethylcellulose, alginate, chitosan...) bonded with silver.

The subject-matter of claims 1-15 differs from D7 in the amount of silver used and therefore is new over D7 according to Art. 54 EPC.

Document D8 describes compositions for the incorporation and stabilization of silver into a polymeric matrix (celluloses, alginates..., see page 11, lines 12-16) for the treatment of wounds and to facilitate and accelerate the wound healing process (see page 11, lines 30-32).

The subject-matter of claims 1-15 differs from D8 by the presence of the complex of the anionic polysaccharide and silver and is therefore new according to Art. 54 EPC.

#### **4. Inventive step**

Document D2 is considered to be the closest prior art. It discloses wound dressings having antibacterial, antiviral and /or antifungal activity which comprises a silver compound in the form of a complex with a hydrophilic polymer (e.g. cellulose derivatives, collagen...) to stabilise against discoloration and dark staining.



The objective technical problem underlying the present invention is to provide a wound dressing having antimicrobial properties and a proliferative effect on wound healing cells.

The proposed solution is a wound dressing comprising a complex of an anionic polysaccharide with silver at a low concentration of 0.1wt% to 3wt%.

Since a technical effect has only been shown with ORC (see examples) and was unexpected, there is no basis for generalising this effect to any anionic polysaccharide. Therefore the above-defined technical problem is not solved over the whole scope of the claims and the subject-matter of claims 9 and 15 is not inventive in the sense of Art. 56 EPC.

#### 4. Further remarks

4.1. The term "about" in combination with ranges used in claims 1, 5, 7-8, 12 and 15 and throughout the description is vague and unclear and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject-matter of said claims unclear (Article 84 EPC).

4.2. The dependency of claim 13 should be corrected.

4.3. The Applicant is requested to file new claims to overcome the abovementioned objections. When filing amended claims, the Applicant should at the same time bring the description into conformity with the amended claims (Rule 34(1)(c) EPC and Guidelines C-II, 7.3). The documents D2-D8 should be identified in the description and its relevant content should be indicated to meet the requirements of Rule 27(1)(b) EPC.

Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).

In order to facilitate the examination on the conformity of the amended application with the requirements of Article 123(2) EPC, the Applicant is requested to clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which



**Bescheld/Protokoll (Anlage)**

Datum  
Date  
Date

27.10.2005

**Communication/Minutes (Annex)**

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**Notification/Procès-verbal (Annexe)**

Anmelde-Nr.:  
Application No.:  
Demande n°:

03 795 068.0

these amendments are based (cf. Guidelines E-II, 1).



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Patents Directorate**

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Your Reference: P031748GB  
Application No: GB0221062.3

1 August 2005

Dear Sirs

**Patents Act 1977: Examination Report under Section 18(3)**

Latest date for reply:

*Feb.*  
**1 December 2005**

I enclose two copies of my examination report and two copies of the new citations.

By the above date you should either file amendments to meet the objections in the enclosed report or make observations on them. If you do not, the application may be refused.

Yours faithfully

Dr Paul Minton  
Examiner



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Your ref : P031748GB  
Application No: GB0221062.3  
Applicant : Johnson & Johnson Medical  
Limited

Examiner : Dr Paul Minton  
Tel : 01633 814732  
Date of report : 1 August 2005

Latest date for reply: 1 December 2005

Page 1/3

## **Patents Act 1977**

### **Examination Report under Section 18(3)**

#### **Basis of the examination**

1. Please be advised that in view of the number of relevant citations already identified, I have decided to defer updating the search pending amendment of your claims. Furthermore, I have not yet considered the non-patent literature identified in the search report of your corresponding PCT application, WO2004/024197.

#### **Novelty**

2. The invention as defined in claims 1-9 and 14-18 is not new because it has already been disclosed in each of the following documents:

GB 0748283 (ION S EXCHANGE AND CHENICAL CORP) - see particularly Example 1.

WO 96/35720 (FIDIA ADVANCED BIOPOLYMERS) - see particularly line 15, page 7 to line 1, page 8 lines 4-12, page 11, and Examples 7-11.

WO 90/10020 (GEDEON RICHTER) see particularly line 23, page 1 to line 3, page 2 and claim 8.

WO 91/11206 (BEAM TECH) see particularly line 18, page 2, line 23, page 2 to line 32, page 3, and claims 1, 3 & 5.

WO 87/05517 (BIO-TECHNOLOGY GENERAL CORP) see particularly Example 1 and claims 1, 3, 7 & 16-17.

WO 96/13282 (INNOVATIVE TECHNOLOGIES) see particularly line 3, page 3 and claims 1 & 8.

WO 02/24240 (ACORDIS) see particularly claims 1, 2, 6-8, 16, 19, 21 & 22.

3. WO96/13282 and WO02/24240 were identified from your equivalent application, WO2004/024197. It is regretted that they were not brought to your attention earlier.



INVESTOR IN PEOPLE

Your ref : P031748GB  
Application No : GB0221062.3

Date of report: 1 August 2005  
Page 2 / 3

[Examination Report contd.]

4. GB0748283 discloses the manufacture of a self-sterilising antiseptic bandage formed by treating a polysaccharide, such as cotton gauze or regenerated cellulose, with an aqueous solution containing silver acetate. WO96/35720 discloses silver salts of a succinic acid hemiester with hyaluronic acid. The Examples demonstrate that the salts are prepared using a solution of a silver compound, e.g.  $\text{AgNO}_3$ , and contain between 23.5% to 31% silver. The salts may be used to treat wounds or burns and can be incorporated into non-woven tissues or gauzes. WO90/10020 discloses a process for preparing a complex by adding a salt to an aqueous solution of a salt of hyaluronate, such as a silver salt. The product is stated to be suitable to treat skin ulcers and other wounds. WO91/11206 discloses an alginate material incorporating silver cations, which can be used as a wound dressing, e.g. for the treatment of leg ulcers. The alginate material may be in the form of a porous fibrous material supported by a textile dressing, which may be treated with a liquid containing the cations. WO97/05517 discloses the use of silver hyaluronate in the treatment of burns, wounds, and soft tissue infection. The product is prepared by reacting sodium hyaluronate with aqueous silver nitrate. The silver content in the salt is experimentally determined to be about 20%.

5. WO96/13282 discloses a wound dressing comprising a wound-contact layer, which may comprise a silver alginate. The layer may be in the form of a woven or nonwoven material or a gel. Meanwhile, WO02/24240 discloses a wound dressing comprising a first fibre, such as carboxymethylcellulose or an alginate to which silver cations are chemically bonded. A second fibre to which no silver is bound is also included. The wound dressing is implied to contain 0.5-25 wt.% of the first fibre. The silver ions may be introduced into the fibre by an ion-exchange process using silver nitrate. The first fibre may be in the form of a nonwoven textile. The wound dressing typically comprises silver cations in an amount from 1.0-2.0% or 0.25-0.75%.

#### Inventive step

6. The invention as defined in claim 10 is obvious in view of what has already been disclosed in GB0748283, WO96/35720, WO91/11206, WO96/13282, and WO02/24240. These documents disclose the use of silver salts of polysaccharides in wound dressings. It is common knowledge that wound dressings should be supplied in a sterile condition and indeed, if this is to be successfully implemented, they must be stored within packaging that ensures that sterility is maintained. Therefore, the subject matter of claim 10 would be obvious to the person skilled in the art.

7. A decision as to whether or not the remaining claims satisfy the requirements with respect to novelty and inventive step has been deferred.



INVESTOR IN PEOPLE

Your ref : P031748GB  
Application No : GB0221062.3

Date of report: 1 August 2005  
Page 3 / 3

[Examination Report contd.]

### Clarity and support

8. Claims 4, 5, 8, 9, and 14 are not considered to have sufficient basis in the description. Thus, in contrast to claim 4, the equivalent text on lines 1-4, page 2 does not envisage mixtures of the polysaccharides listed. Moreover, the range specified in claim 5 is not envisaged in the corresponding disclosure on lines 28-31, page 2. Similarly, the ranges mentioned in claims 8-9 are not explicitly disclosed in the equivalent passage in lines 24-28, page 3. Meanwhile, the statement of invention on lines 7-9, page 6 refers to a dressing whilst independent claim 14 discloses a medicament.

9. The word "about" when used in combination with a numerical range should be avoided as it casts doubt as to the intended scope. Therefore, it should be removed from claims 5, 8, and 9.

10. There is no antecedence for the "wound dressing" of claim 16 in any of the preceding "use" claims. In particular, claim 14 to which claim 16 is dependent refers to a medicament rather than a dressing.

11. The statement of invention on lines 14-20, page 6 does not correspond to any of the independent claims and should be deleted. It should also be noted that a method of treating a wound by applying a wound dressing comprising the silver-polysaccharide complex is considered to be equivalent to the use of such a complex in a dressing for the treatment of wounds (lines 7-9, page 6).

### Registered Trade Marks

12. Although they should preferably be avoided, if you wish to keep the references to the Registered Trade Marks FRYMA and WARING on pages 11-12 of your specification, you should acknowledge that they are Registered Trade Marks, possibly by using the abbreviation "(RTM)". If you do not insert an acknowledgment, I will do so in manuscript.

### Conflict with a corresponding European patent application

13. This application appears to be similar to your European patent application published under number EP1536845, having the same priority date and designating GB. If patents granted on these two applications relate to the same invention, the Comptroller will in due course revoke the patent granted on the present application unless either you amend the present specification to remove the conflict or, before the date of grant of the present application under Section 25(1), you begin proceedings to surrender the European patent (UK). Of course if the GB designation is withdrawn before the grant of the European patent, no action will be required under Section 73(2).